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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,735	03/30/2005	Gavriel J. Iddan	P-4409-US	1893

49443 7590 04/16/2009

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EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
04/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,735	IDDAN ET AL.	
	Examiner	Art Unit	
	RENE TOWA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,18,24-30,32,33,35,36,38-40,43-48 and 50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,18,24-30,32,33,35,36,38-40,43-48 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/07/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to a preliminary amendment filed March 30, 2005. Claims 1-15, 18, 24-30, 32-33, 35-36, 38-40, 43-48 and 50 are pending. Claims 16-17, 19-23, 31, 34, 37, 41-42 and 49 have been cancelled.

Claim Objections

2. Claim 33 is objected to because of the following informalities:

at lines 1-2 of the claim, the limitations "the housing" appears to lack sufficient antecedent basis and should apparently read --the outer covering-- as per claim 32 from which it depends.

Appropriate correction is required.

Double Patenting

3. Claim 10 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 3. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claims 1, 3, 7, 10-14, 24-30, 32, 35-36, 40, 43-48 & 50** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mullick et al. (US 2003/0167000) in view of Canton (US 6,145,393).

Mullick et al. disclose an in-vivo sensing system comprising:

(a) a housing 42 (see figs. 2 & 3A-B; par 0055-0056);

wherein the housing 42 has a capsule shape (see figs. 2 & 3A-B);

wherein the housing is at least partially transparent (i.e. “transparent window 62”) (see fig. 2);

(b) a sensing device 48 (see par 0059);

wherein the sensing device includes an imaging device (see par 0059);

(c) a transmitter 50 (see par 0062); and,

(d) a ballast weight (see par 0019; par 0065);

The Examiner notes that Mullick et al. teach an in-vivo sensing system that "may be weighted in such a way as to maintain a particular orientation in the stomach" (see par 0019); Mullick et al. further teaches that the ballast weight may be the power source or battery 54 to orient the in-vivo sensing system in the stomach (see par 0065);

Mullick et al. further teach a method for sensing an in-vivo site (see par 0018) comprising the steps of:

(i) enabling an in-vivo sensing system 40 disposed within a housing 42 to be moved within the anatomy of a patient (see par 0055); wherein the in-vivo sensing system 40 includes an imaging device 48 (see par 0059);

(ii) applying an external force (i.e. "gravitational force") to the in-vivo sensing system 40; wherein applying an external force includes repositioning the patient;

The Examiner notes that Mullick et al. teach an in-vivo system that performs diagnostic operations within the stomach of a patient while the patient performs activities of daily living (see par 0015) for a maximum of 72 hours (see par 0020); as such, both the patient and the in-vivo system are inherently subject to the gravitational force while the patient repositions while conducting the activities of daily living.

(iii) transmitting data from the in-vivo sensing system 40 (see par 0019); and,

(iv) reviewing data the transmitted data (see par 0021); and,

(v) applying an external force to change the direction of the imaging device 48 (i.e. "controlled mobility") based on the reviewed transmitted data (see par 0087).

The Examiner notes that Mullick et al. teach an in-vivo system comprising an imaging system that tracks the position of the in-vivo system (see par 0061); wherein an operator can externally "re-orient" the imaging system thereof (see par 0087). As such, the Examiner submits that Mullick et al. inherently applies an external force to change the direction of imaging device based on the reviewed data (i.e. the reviewed data may only pertain to the position and/or orientation of the in-vivo capsule, which may then be "re-oriented" externally by a physician).

Mullick et al. teach an in-vivo sensing system, as described above, that fails to explicitly teach an optical stabilization platform comprising at least one friction reducing mechanism or liquid, at least one ballast weight or at least one directional activator.

However, **Canton** discloses a sensing device comprising an optical platform including:

(a) a housing 16 (see fig. 10);

(b) at least one friction reducing mechanism 18 (see fig. 10);

wherein the friction-reducing mechanism 18 includes a liquid;

wherein the liquid 18 has a diffraction coefficient substantially similar to a diffraction coefficient of the housing 16;

wherein the liquid 18 is at least partially transparent;

wherein the liquid is oil (see; at least one friction reducing mechanism 18;

wherein the friction-reducing mechanism 18 includes a liquid;

wherein the liquid 18 has a diffraction coefficient substantially similar to a diffraction coefficient of the housing 16;

wherein the liquid 18 is at least partially transparent;

wherein the liquid is oil (see col. 4, lines 52-65);

(c) a sensing device 20 (see fig. 10);

wherein the sensing device 20 has a weight that is evenly distributed along a horizontal and a vertical axis of the sensing device 20 (see col. 4, lines 16-20);

wherein the sensing device 20 has a specific gravity that does not substantially exceed the specific gravity of the liquid 18 (see col. 4, lines 6-8);

wherein the liquid is introduced into the housing 16 during use (col. 6, lines 19-24, 31-42 & 51-57);

wherein the sensing device 20 includes an imaging device 20 (see col. 8, lines 14-15);

wherein the imaging device includes a ballast weight (see col. 4, lines 20-31); and,

(d) at least one directional activator (17A-B) (see fig. 10);

wherein the directional activator comprises at least one magnet (17A-B) (see col. 7, lines 1-10).

In regards to **claims 1, 3, 7, 10, 24-26, 30, 32, 40, 43-48 & 50**, Mullick et al. teach a vehicular in-vivo system that can include a machined mechanical stabilization platform that can be built into the imaging system to stabilize the image (see par 0087); since Canton teaches a sensing device having a stabilization platform for stabilizing images (see col. 1, lines 8-10) that could be mounted on a vehicular device (see col. 3, lines 44-48), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Mullick et al. with an optical platform having a friction reducing mechanism as taught by Canton in order to achieve an in-vivo system having an imaging device that is able to float in neutral buoyancy thereby stabilizing images recorded by the moving imaging device.

Similarly, in regards to **claims 11-12**, Mullick et al. teach an in-vivo system that includes a ballast to orient the capsule in the stomach (see par 0065); since Canton teaches a sensing device having a weight that is evenly distributed along a horizontal and vertical axis of the sensing device (see col. 4, lines 16-20 & 29-32), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was

made to provide the system of Mullick et al. with a weight that is evenly distributed along a horizontal and vertical axis as taught by Canton in order to position the imaging device at the physical center of the system so as to achieve an imaging device that will not occur if acceleration forces are applied to the system.

In regards to **claims 13-14 & 35-36**, Mullick et al. teach an image stabilization system that includes miniature motors to allow the imaging system to be reoriented (see par 0087); since Canton teaches a pair of magnets for repositioning the imaging device 20 with respect to the viewing port 23 (see fig. 10; col. 7, lines 1-10), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Mullick et al. with a pair of magnets as taught by Canton in order to selectively reorient the imaging device.

In regards to **claim 27**, Mullick et al. teach an in-vivo sensing device that allows the in-vivo sensing device (i.e. “imaging system”) to be reoriented, which could include a remote control (see par 0087); since Canton teaches a sensing device that can become misaligned with viewing port 19 of the housing 16 (see col. 5, lines 1-7) such that a pump 29 would thrust the friction reducing liquid 18 into the housing 16 to correct the misalignment or orient the sensing device 20 to observe through any portion of the hemisphere of the viewing port 19 of the housing 16 (see col. 6, lines 5-11, 19-24, 31-42 & 51-57), it would have been obvious to one of ordinary skill in the art at the time Applicant’s invention was made to provide the system of Mullick et al. with a liquid that is introduced during use as taught by Canton in order to correct any misalignment

occurring during use or to orient the sensing device to observe through any portion of the hemisphere of the viewing port.

In regards to **claims 28-29**, since Canton teaches a sensing device wherein the liquid has similar optical properties as the viewing port 19 of the housing 16 so that the liquid must also be transparent (i.e. similar diffraction coefficient of the housing) to the wavelengths of light required by the imaging system (see col. 4, lines 56-65), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Mullick et al. with a liquid having a diffraction coefficient that is substantially to a diffraction coefficient of the housing as taught by Canton in order to allow the liquid and the housing to be transparent to the wavelengths of light required by the imaging system.

6. **Claim 2** is rejected under 35 U.S.C. 103(a) as being unpatentable over Mullick et al. ('000) in view of Canton ('393), and further in view of Von Alten (US 6,929,636).

Mullick et al. as modified by Canton disclose an in-vivo system, as described above, that fails to explicitly teach a housing that includes a material consisting of glass, plastic or rubber.

However, **Von Alten** teaches an in-vivo system comprising an inert housing that includes a material consisting of glass (see figs. 1-2; col. 5, lines 27-30).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Mullick et al. as modified by Canton with a housing that includes glass as taught by Von Alten in order to achieve a housing that is inert or biocompatible in the human body.

7. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Mullick et al. ('000) in view of Canton ('393), and further in view of Bucalo (US 4,172,446).

Mullick et al. as modified by Canton disclose an in-vivo system, as described above, that fails to explicitly teach a collapsible housing.

However, **Bucalo** discloses an in-vivo system comprising a collapsible housing 20 (see fig. 1; col. 3, lines 40-60).

Mullick et al. teach an in-vivo system comprising a suction port 500 to remove unwanted debris from the gastrointestinal tract to improve or enhance visualization, diagnostic, therapeutic or other functions of the capsule (see fig. 12; par 0082); since Bucalo teaches an in-vivo system comprising a pre-collapsed housing for generating suction in-vivo based on a condition prevailing in the body cavity (see col. 3, lines 40-60), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Mullick et al. as modified by Canton with a collapsible housing as taught by Bucalo in order to achieve a suction generating mechanism that is activated based on a condition prevailing in the body cavity in-vivo to improve or enhance visualization, diagnostic or therapeutic functions of the in-vivo system.

8. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Mullick et al. ('000) in view of Canton ('393), Bucalo ('446) and further in view of Kovacs et al. (US 5,833,603).

Mullick et al. as modified by Canton and Bucalo disclose an in-vivo system, as described above, that fails to explicitly teach a semi-permeable housing.

However, **Kovacs et al.** disclose an in-vivo system comprising a housing 126 that is collapsible and semi-permeable (see figs. 10-11; col. 15, lines 25-49).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Mullick et al. as modified by Canton and Bucalo with a semi-permeable membrane as taught by Kovacs et al. in order to achieve an ion-selective selective chemical sensor using an electrochemical measurement such as impedance, spectroscopy, voltammetry, and amperometry.

9. **Claims 6, 8-9, 18, 33 & 38-39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mullick et al. ('000) in view of Canton ('393), and further in view of Kilcoyne et al. (US 6,285,897).

Mullick et al. as modified by Canton disclose an in-vivo system, as described above, that fails to explicitly teach an attachment mechanism or a pH sensor.

However, **Kilcoyne et al.** disclose an in-vivo system (see col. 3, lines 6-10) comprising:

(a) a housing 120:

wherein the housing 120 is an inert hydrocarbon (i.e. polyethylene) (see col. 6, lines 55-62);

(b) an attachment mechanism (see fig. 6) comprising anchors or fasteners such as tacks, pins, hooks, barbs, sutures, clips, staples (see col. 9, lines 5-51) or glue such as an adhesive (see col. 8, lines 48-60); and,

(c) at least one sensor (i.e. pH, temperature or pressure sensor) (see col. 5, lines 15-46).

In regards to **claim 6**, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Mullick et al. as modified by Canton with a housing that includes a hydrocarbon as taught by Kilcoyne et al. in order to achieve a housing that is inert or biocompatible in the human body.

In regards to **claims 8-9 & 33**, Mullick et al. teach an in-vivo system comprising a plurality of retractable prongs 180 to effectively anchor or stabilize the in-vivo system (see fig. 8; par 0073); since Kilcoyne et al. teach other means for effectively anchoring an in-vivo system in the gastrointestinal track of a patient (see fig. 6), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Mullick et al. as modified by Canton with an attachment mechanism as taught by Kilcoyne et al. in order to temporarily attach, anchor or stabilize the in-vivo device to the body lumen so as to collect physiological data therefrom.

In regards to **claims 18 & 38-39**, similarly, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Mullick et al. as modified by Canton with a pH sensor as taught by Kilcoyne et al. in order to achieve long-term monitoring of gastroesophageal reflux (GERD).

10. **Claim 15** is rejected under 35 U.S.C. 103(a) as being unpatentable over Mullick et al. ('000) in view of Canton ('393), and further in view of DiCarlo (US 2003/0004562).

Mullick et al. as modified by Canton disclose an in-vivo system, as described above, that fails to explicitly teach a magnetic switch.

However, **DiCarlo** discloses an in-vivo sensing system (see par 0030) comprising a remote-activatable magnetic switch 34 (see fig. 2; par 0032-0033).

Since Mullick et al. teach an in-vivo sensing device that allows the in-vivo sensing device (i.e. "imaging system") to be reoriented, which could include a remote control (see par 0087) and Canton teaches a sensing device that can be selectively repositioned or rotated using a set of electromagnets magnetic (see fig. 10; col. 7, lines 1-10), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Mullick et al. as modified by Canton with a magnetic switch as taught by DiCarlo in order to achieve an in-vivo sensing device that can selectively be reoriented remotely; for example, similar to Mullick et al., Canton teaches a sensing device 20 that can be pointed to observe through any portion of the hemisphere of the viewing port 19 (see fig. 10; col. 6, lines 51-57); as such, the magnetic switch 34 of DiCarlo may serve as means to override to the microprocessor 29, which is mainly concerned with realignment of the viewing ports (23, 29), in order to point the sensing device 20 to observe through any portion of the hemisphere of the viewing port 19.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rene Towa/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736